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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/081,116	02/21/2002	Roy Wade Bowman	03221.0003U2	8546

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EXAMINER	
ISABELLA, DAVID J	
ART UNIT	**PAPER NUMBER**
3738	

DATE MAILED: 01/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/081,116	BOWMAN ET AL.	
	Examiner	Art Unit	
	DAVID J ISABELLA	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 November 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *20-44* is/are pending in the application.

4a) Of the above claim(s) *34-44* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *20-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Election/Restrictions

Newly submitted claims 34-44 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: ***

Claims 34-38,40-44 are directed to a process for manufacturing a two layer prosthesis including the step of passing a ***non-crosslinking*** self shaping dispersion through the first fill opening; and claim 39 is directed to passing a non-crosslinking self shaping dispersion through the first fill opening by vacuum pumping.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 34-44 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 20,25,26,27 are rejected under 35 U.S.C. 102(b) as anticipated by Wild (2204490 CA).

Wild discloses a breast prosthesis having a first section and a second section.

Wild discloses a process for manufacturing a two layer breast prosthesis comprising the steps of: providing: (i) a first film envelope configured to define a first interior volume; and (ii) a second film envelope joined to the first film envelope along a common side edge to thereby define a second interior volume wherein said second film envelope and said first film envelope share a common interstitial film wall and wherein said first and said second film envelopes further comprise a respective first and a second fill opening at least partially filling the second interior volume of step a) by passing a curable elastic material precursor through the second fill opening; at least partially filling the first interior volume of step a) by passing a self- shaping dispersion through the first fill opening, sealing the first and second till openings; curing the elastic material precursor in the second film envelope to provide a two- layer breast prosthesis comprising a cured elastic material laver and an uncured self-shaping layer.

Claims 25-27, see pages 3 and 4 of Wild.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 20-27 , are rejected under 35 U.S.C. 103(a) as being unpatentable over Wild (2204490 CA) in view of Snyder, Jr (5902335).

Wild discloses a process for manufacturing a two layer breast prosthesis comprising the steps of: providing: (i) a first film envelope configured to define a first interior volume; and (ii) a second film envelope joined to the first film envelope along a common side edge to thereby define a second interior volume wherein said second film envelope and said first film envelope share a common interstitial film wall and wherein said first and said second film envelopes further comprise a respective first and a second fill opening at least partially filling the second interior volume of step a) by passing a curable elastic material precursor through the second fill opening; at least partially filling the first interior volume of step a) by passing a self- shaping dispersion through the first fill opening, sealing the first and second till openings; curing the elastic material precursor in the second film envelope to provide a two- layer breast prosthesis comprising a cured elastic material laver and an uncured self-shaping layer. While Wild generally discloses a process for making a two layered breast prosthesis, Wild fails to specifically set forth manufacturing steps for making the same.

Snyder, Jr. teaches a lightweight breast prosthesis having a first section and a second section. The first section has a gel-like consistency and the second section has a density reducing agent to provide lightweight prosthesis. Snyder provides more detailed manufacturing process for forming a two layered breast form. The prosthesis is formed from a backing film, outer sheet and inner sheet forming a first and second chamber. The prosthesis is made by making a mold having ther shape of the outer

surface. The cavity is filled with mixture of gel reactants and microspheres which is heat cured. The first cavity is filled with heat curable materials. The sheets can be welded with access holes being provided into each cavity to provide for the charging of the interior volumes with the appropiate reactants. If not inherent in Wild, to use the steps as outlined by Snyder, Jr for manufacturing the breast prosthesis of Wild would have been obvious to one of ordinary skill in the art as one possible method for producing a two-layer prosthesis.

Claim 21, the steps as claimed is disclosed by Synder, Jr. See columns 4 and 5.

Claim 22, The holes of Synder, Jr are sealed prior to curing. In so far as definite, it appears that this step meets the limitation as claimed.

Claim 23, see film 34.

Claim 24, see column 2, lines 5+.

Claims 25, see columns 2, lines 18+ and column 3, lines 35+.

Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wild in view of Synder, Jr as applied to claim 26 above, and further in view of Shaw (4380569).

While Wild generally discloses the use of microspheres in the formation of a two layer breast prosthesis, Wild is silent as to the physical dimension of the microspheres. Shaw teaches the use of microspheres in the manufacturing of a prosthesis and teaches a range of spherical diameters encompassing the range as claimed by applicant. In light of the teaching of Shaw, one with ordinary skill in the art would look to

Shaw to provide a guidance in selecting a range of spherical diameters to effect the desired properties suitable to mimic the breast form.

Claims 29 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wild in view of Synder, Jr as applied to claim 26 above, and further in view of Wild (5738812).

While Wild generally discloses the use of microspheres in the formation of a two layer breast prosthesis, Wild is silent as to the viscosity of the microspheres/silicone mixture. Wild (5738812) teaches the use of microspheres in the manufacturing of a prosthesis and teaches a range of viscosity encompassing the range as claimed by applicant. In light of the teaching of Wild (5738812), one with ordinary skill in the art would look to Wild to provide a guidance in selecting a range of viscosity to effect the desired properties suitable to mimic the breast form.

Claims 31-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wild in view of Synder, Jr as applied to claim 20 above, and further in view of Loi (4701230).

The concept for removing air from the dispersion within the sealed shell is taught by Loi. To obtain a more accurate profile and viscosity prosthesis by removing air from within the sealed shell of Wild would have been obvious from the teachings of Loi.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DAVID J ISABELLA whose telephone number is 703-308-3060. The examiner can normally be reached on MONDAY-THURSDAY.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, CORRINE MCDERMOTT can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

DAVID J ISABELLA
Primary Examiner
Art Unit 3738

DJI
1/5/2005